Medtronic

Living with the Aurora EV-ICD™ system

Have you had a heart attack? Do you have heart failure? Have you been diagnosed with a fast heartbeat (tachycardia)?

If so, this brochure can help you understand your heart condition and treatment options. It provides basic information about sudden cardiac arrest (SCA). It also explains implantable defibrillators, and what to expect before and after you have one placed.

Ask your doctor about your unique medical condition and treatment options.

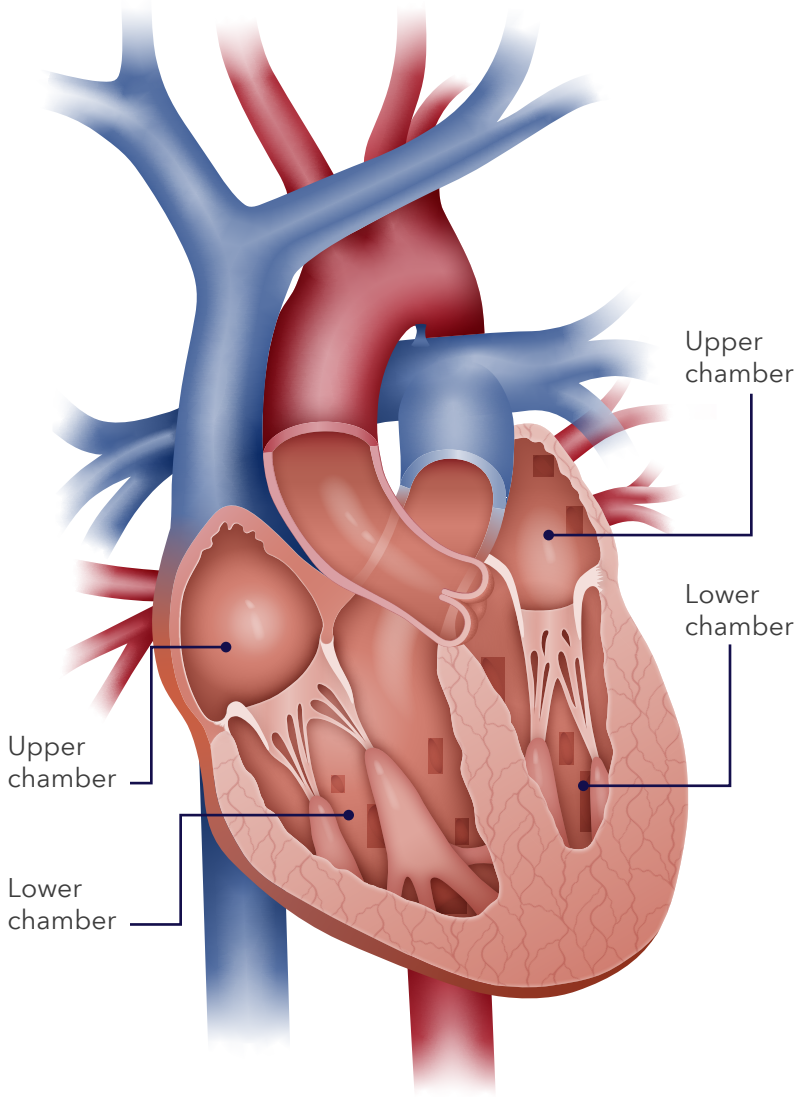
What is tachycardia?

Tachycardia is a condition where the heart beats too fast. A healthy heart beats 60 to 100 times per minute, pumping about 75 gallons of blood every hour. Exercise, stress, or fear can cause the heart to beat faster, but this is a normal response. With tachycardia, the heart beats more than 100 times per minute, and can beat as fast as 400 times per minute, for no specific reason. At this rate the heart is not able to pump blood effectively to the body and brain.

There are different types of fast heart rhythms that can occur in either the upper chambers (atria) or lower chambers (ventricles) of the heart.

- Atrial flutter and atrial fibrillation (AFib) start in the upper chambers of the heart.
- Ventricular tachycardia and ventricular fibrillation start in the lower chambers of the heart.

Learn more about tachycardia



What is SCA?

SCA is an electrical problem with the heart that causes a dangerously fast heart rhythm (ventricular fibrillation). The rapid, irregular heart rhythm causes the heart to quiver rather than pump. When the heart stops pumping blood, oxygen cannot reach the body and brain. If not treated immediately, SCA is usually fatal.

One of the nation's top killers, SCA claims more lives than breast cancer or lung cancer.[1]

436,000[2]

lives are claimed by SCA in the United States every year or > **one life every 90 seconds**[2] **–** that's equal to five football stadiums full of people.

Learn more about sudden cardiac arrest

Heart attack and SCA: What are the differences?

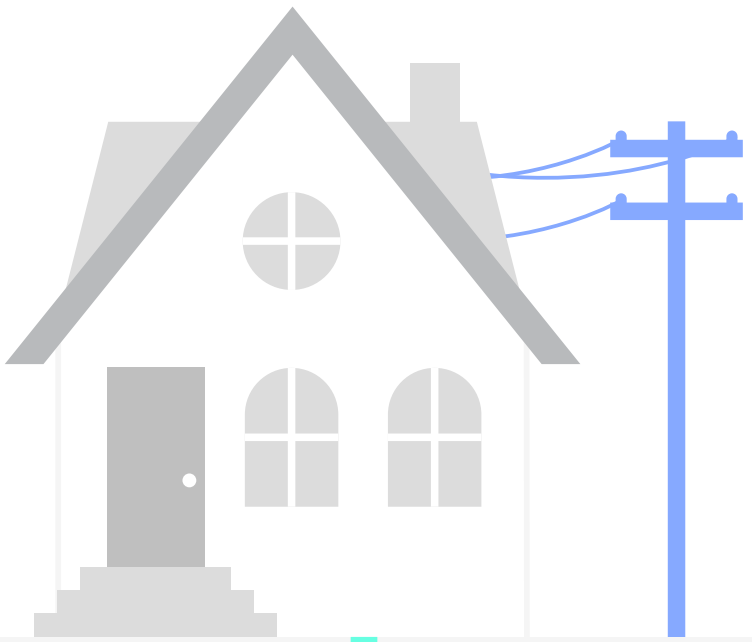
SCA is not the same as a heart attack, although the two are often confused. Think of your heart as a house.

SCA is an electrical issue.

SCA is a rhythm problem that prevents the heart from pumping blood to the brain and organs.

A heart attack is a plumbing issue.

A heart attack is typically caused by a blockage in a blood vessel to the heart muscle. This can permanently damage part of the heart and can lead to SCA.



What could put someone at risk of having SCA?

- Previous heart attack or SCA
- Family history of SCA or other heart disease
- Heart failure
- Low ejection fraction (this is explained on the next page)
- Rapid or abnormal heartbeats starting in the bottom chambers of the heart

What are symptoms of SCA?

- Loss of consciousness
- Dizziness
- Fast heartbeat

EF number:
a number you should know

EF stands for "ejection fraction." It is the percentage of blood that is pumped out of the heart with each heartbeat. Your doctor knows how well your heart is pumping based on your EF number. It is important for you and your doctor to check your EF regularly.

A healthy heart has an EF between 55% and 70%.[3] This indicates the heart is pumping well and can deliver enough blood to the body and brain. Even a healthy heart does not pump 100% of blood out of the heart during each beat – some blood always remains in the heart.

People with a low EF – 35% or below – are at an increased risk for SCA.[4]

How is EF measured?

The most common way to measure EF is with an echocardiogram, which is a test usually performed in a doctor's office or hospital's diagnostic area.

Typical EF ranges[3]:

55–70% Heart's pumping ability is **NORMAL**

40–55% Heart's pumping ability is **BELOW NORMAL**

40% or below Heart's pumping ability is **LOW**

Treating SCA with defibrillation

If not treated immediately, SCA can be fatal. In fact, SCA is fatal in 95% of people who experience it outside of a hospital.[5]

The best way to treat SCA is with defibrillation. Defibrillation delivers an electrical shock to your heart to restore a normal heartbeat.

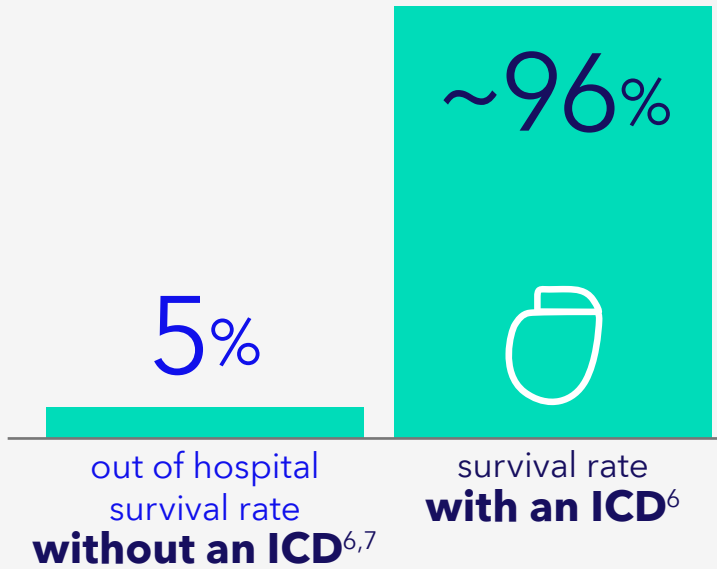
Automated external defibrillator (AED)

There are two primary forms of defibrillation:

1. An automated external defibrillator, or AED, is a portable device that measures the heart's electrical activity. It is used by emergency response teams or the general public to shock the heart.

   During an SCA a bystander can find and use an AED, but it often takes several minutes to locate a nearby AED and use it. This precious lost time lowers the odds of survival.

2. An implantable defibrillator, or ICD, is a device that is implanted under the skin. During an SCA, an ICD delivers lifesaving treatment on its own, often in fewer than 10 seconds.



out of hospital survival rate **without an ICD**[6,7]

survival rate **with an ICD**[6]

Implantable cardioverter defibrillator (ICD)


ICD lead

What is an ICD?

An ICD system has two parts: the defibrillator and leads.

- A defibrillator continuously monitors the heart and automatically corrects heart rhythms.
- Leads are thin, soft, insulated wires about the size of a spaghetti noodle. They carry the electrical impulse from the ICD to your heart. They also send information about the heart's natural activity back to the ICD.

What is the Aurora EV-ICD system?

The Aurora EV-ICD is an extravascular implantable cardioverter defibrillator (ICD). With a traditional ICD, the lead is placed in the heart through a vein. Aurora EV-ICD is designed to avoid certain risks of traditional, transvenous ICDs because its lead is placed outside the heart and veins, under the breastbone. The Aurora EV-ICD is implanted below the left armpit. The procedure is performed under general anesthesia and patients typically return home within 24 hours.

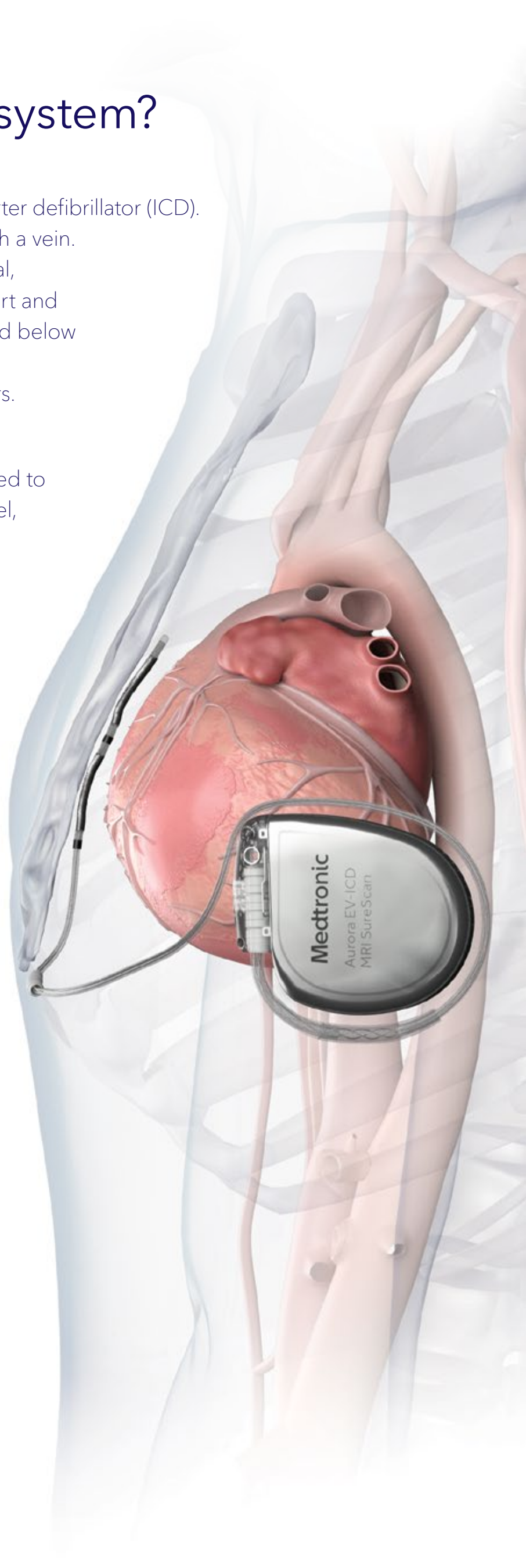
The energy needed for the Aurora EV-ICD to work comes from a battery that is sealed inside the device and is projected to last more than 10 years.[†8] When the battery falls to a low level, the device will need to be replaced. The lead may not need to be replaced at the same time. Your doctor will discuss with you whether the lead should be replaced.

How does the Aurora EV-ICD work?

The Aurora EV-ICD monitors a patient's heartbeat 24 hours a day. If the heart is beating too fast or is not beating regularly, the device first sends small electrical signals to correct the heart rate. This is called antitachycardia pacing or ATP. If the fast heartbeat continues, the device then sends an electric shock to reset the normal heartbeat. This electric shock is called defibrillation.

Life with the Aurora EV-ICD

After recovering from the implant procedure most people are able to resume their normal, daily activities. Work with your doctor to develop a plan, discuss when you can return to your normal activities, and which activities you should avoid.



Risks for Aurora EV-ICD system may include: lead dislodgement, surgical complications, infection, failure to deliver therapy when it is needed, and/or receiving extra therapy when it is not needed.

[†]Projected battery longevity estimates are based on accelerated battery discharge data and device modeling. Results for individual patients vary based on programmed parameters and features.

Contact your doctor immediately if:

- The area around the incision becomes red, moist, or begins to swell.
- Your EV-ICD starts to beep. The EV-ICD performs regular, automatic self-checks. If it starts to beep, something needs attention. Contact your doctor as soon as possible for instructions.

If you are close to a magnet, your device may make a solid beep, which does not require a call to the clinic.

You do not need to contact your doctor if you hear a solid, 10-second sound. This means that your EV-ICD came close to a strong magnet. You can simply move the magnet away from your EV-ICD and carry on with your day.

What does a shock from an EV-ICD feel like?

A shock from an EV-ICD can feel like a sharp or quick thump to the chest, but people feel the shock differently. The muscles in your chest and upper arm may tighten so strongly that you jump up in surprise. Try not to worry if this happens. It simply means that the EV-ICD is doing its job. Anyone touching you at the time you get the shock may feel a muscle spasm or a tingle. It will not hurt the person touching you.

What is a shock plan?

Your doctor should work with you to create a shock plan, which will be your guide to follow if you feel a shock from your EV-ICD. Shock plans may vary depending on your condition and local facilities.

Work with your doctor to create a shock plan. These are things you might want to discuss:

- What to do if you experience a shock
- What to do if you experience more than one shock in a 24-hour period
- What to do if you experience pain, shortness of breath, lightheadedness, confusion, dizziness, or fast heartbeat

Harrison
Medtronic EV-ICD patient

Watch Harrison's Story

Not every person will receive the same results. Talk to your doctor about your treatment options.

Risks for Aurora EV-ICD system may include: lead dislodgement, surgical complications, infection, failure to deliver therapy when it is needed, and/or receiving extra therapy when it is not needed.

Remote monitoring for implanted heart devices

If you have an implanted heart device, ongoing care doesn't end at the implant. It's important to maintain a connection with your doctor or clinic for the life of your device. One of the best ways to do this is through remote monitoring.

Remote monitoring is a way for your implanted heart device to communicate with your doctor or clinic, potentially lowering the number of times you have to travel to your clinic for a device check.

Learn more about remote monitoring

Common questions

Can I use a cell phone?[8]

Yes, cell phones and other mobile devices are safe to use if you maintain proper distance between them and your Aurora EV-ICD. When using a cell phone, tablet computer, or other mobile device, keep it six inches from your EV-ICD. Use your phone on the ear opposite your EV-ICD and avoid placing the cell phone in a pocket near your EV-ICD.

Are household appliances safe to use?[8]

Yes. Most household appliances and items are safe to use as long as they are properly maintained and in good working order. This includes microwave ovens, major appliances, electric blankets, and heating pads.

Please read the patient manual for a list of these items and the specific distances that they should be kept away from your EV-ICD.

Will magnets affect my device?[8]

Yes. Your EV-ICD is designed to change programming modes when it is very close to a magnet. This feature is typically used by your physician, but should be avoided in your daily life. For this reason, keep any items containing magnets at least six inches away from your Aurora system. If you do come into close contact with a magnet, your EV-ICD will emit a 10-second solid tone. This is just a warning. Simply move the magnet away from your chest and go about your day.

Can I get an MRI (magnetic resonance imaging)?[8]

People with an EV-ICD should always let their doctor know that they have an implantable heart device when planning to get an MRI. The Aurora EV-ICD is FDA approved for use in the MRI environment as long as certain conditions are met. Work with your doctor to ensure that you meet these criteria.

Can I travel?[8]

Yes. Make sure you carry your device ID card when traveling and tell airline security personnel that you have an implanted heart device.

Then, simply walk through security archways at a normal pace. Don't stop under or touch the archway as you pass through. Full-body scanners are safe to use as instructed. If a handheld wand is used, ask the security operator not to hold it over your device or wave it back and forth repeatedly over your device.

You can show your device ID card to security personnel and ask for hand screening instead if you prefer.

Can I return to my normal activities and intimacy?[8]

Having an EV-ICD will not prevent you from getting back to most activities and hobbies: bowling, golfing, playing tennis, gardening, fishing, and more. But the heart condition your EV-ICD is treating might affect what you can do. Discuss any limitations you may have with your doctor.

Most people are able to return to work. The timing will depend on many things, including the type of work you do. Make this decision together with your doctor.

People usually get back to sexual activity when they feel comfortable. Your EV-ICD will allow your heartbeat to rise normally, for example when having sex, without giving you a shock. If you receive a shock during intercourse, stop and contact your doctor. Your doctor will determine what caused the shock and can make changes to the EV-ICD settings if needed.

Risks for Aurora EV-ICD system may include:
lead dislodgement, surgical complications, infection, failure to deliver therapy when it is needed, and/or receiving extra therapy when it is not needed.

Get heart device answers

If you or a loved one have questions about living with a heart device, please visit HeartDeviceAnswers.com or scan the QR code above. Once on the site, simply type in a word, phrase, or question or explore a list of topics to find the answers you're looking for.

Visit Heart Device Answers

Resources

Medtronic Patient Services

If you have a Medtronic cardiac device and want to learn more or have questions about living with an ICD, please contact Medtronic Patient Services at 1-800-551-5544. Our Patient Services Specialists are available to assist you, Monday–Friday from 7 a.m. to 6 p.m. CT.

Medtronic.com/ICD

Helpful information on Medtronic ICDs can be found on this website.

Visit medtronic.com/ICD

Refer to the patient manual or speak to your doctor for additional information about the Aurora EV-ICD system.

Patient Services

Medtronic
8200 Coral Sea St. NE MVC31
Mounds View, MN 55112

Patient toll-free line:
1.800.551.5544
Fax: 763.367.5809

7:00 a.m. to 6:00 p.m. CT
Monday–Friday

References

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[2] CPR Facts & Stats. American Heart Association. Available at: https://cpr.heart.org/en/resources/cpr-facts-and-stats. Accessed October 24, 2023.

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[5] Roger VL, Go AS, Lloyd-Jones DM, et al. Heart disease and stroke statistics – 2012 update: a report from the American Heart Association. [published correction appears in *Circulation.* 2012;125:e1002]. *Circulation.* January 3, 2012;125(1):e2-e220.

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[7] Zipes DP, Roberts D. Results of the international study of the implantable pacemaker cardioverter-defibrillator. A comparison of epicardial and endocardial lead systems. The Pacemaker-Cardioverter-Defibrillator Investigators. *Circulation.* July 1, 1995;92(1):59-65.

[8] Medtronic Aurora EV-ICD™ MRI SureScan™ DVEA3E4 Device Manual.

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Important Safety Information

Brief Statement for Aurora EV-ICD™ MRI SureScan™ System and Associated Tunneling Tools

An implantable defibrillation (ICD) system relieves symptoms of heart rhythm disturbances. They do this by restoring normal heart rates. A normal heart rate provides your body with the proper amount of blood circulation. The defibrillation system is intended for patients who are at risk for a potentially life-threatening heart rhythm.

Risks associated with a defibrillation system include, but are not limited to, infection at the surgical site and/or sensitivity to the device material, failure to deliver therapy when it is needed, or receiving extra therapy when it is not needed. After receiving an implantable defibrillation system, you may have limitations with magnetic and electromagnetic radiation, electrical or gas-powered appliances, and tools with which you are allowed to be in contact.

A complete Aurora Extravascular Implantable Cardiac Defibrillation (EV-ICD) MRI SureScan system consists of a specified combination of an Aurora EV-ICD device with the corresponding Epsila lead. Any other combination of device and lead could result in the inability for the device to function and lead to patient harm.

When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate defibrillation therapy. The Aurora EV-ICD MRI SureScan system is MR conditional. This means the defibrillation system is designed to allow patients to undergo MRI, when your doctor determines you meet patient eligibility requirements and the scan is conducted according to Medtronic directions.

This treatment is prescribed by your physician. This treatment is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this treatment, results may vary.

For further questions or additional information, please call the Medtronic toll-free number at 800-551-5554 (7:00 a.m. to 6:00 p.m., Monday-Friday, Central time) or see the Medtronic website at medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

Medtronic MyCareLink™ Patient Monitor, Medtronic CareLink™ Monitor and Medtronic CareLink™ Patient Information Site

The Medtronic MyCareLink Patient Monitor and the CareLink Monitor are prescription devices indicated for use in the transfer of patient data from some Medtronic implantable cardiac devices based on physician instructions and as described in the product manuals. The CareLink Patient Information Site is intended to provide patients, their friends/family, and caregivers messages regarding transmission status of patient device diagnostic data to the CareLink Network. Transmissions to the CareLink Network sent via cellular connectivity are subject to cellular service availability. The monitor must be on and in range of the device in order to wirelessly receive data from your implanted device. Web browsers currently supported by the CareLink Patient Information Site are: Microsoft® Internet Explorer for Windows Version 8.x and Version 9.x, Mozilla Firefox® for Windows Version 13.x, Google Chrome™ for Windows Version 20.x. CareLink Patient Information Site availability may be unavailable at times due to maintenance or updates, or due to coverage being unavailable in your area. These products are not a substitute for appropriate medical attention in the event of an emergency and should only be used as directed by a physician.

The Medtronic CareLink Service is prescribed by your physician. This service is not for everyone. Please talk to your doctor to see if it is right for you. Your physician should discuss all potential benefits and risks with you. Although many patients benefit from the use of this service, results may vary. For further information, please call CareLink Patient Services at 1 (800) 929-4043 (8:00 a.m. to 5:00 p.m., Monday–Friday, Central time) or see the Medtronic website at medtronic.com.